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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,649	02/10/2004	Douglas Charles Hanson	ABXPF1 DIV2	5045

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EXAMINER

OUSPENSKI, ILIA I

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/776,649

Applicant(s)

HANSON ET AL.

Examiner

ILIA OUSPENSKI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/9/2004, 5/25/2005, 7/27/2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 105-366 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 105-366 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/27/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of the Species of anti-CTLA-4 antibody 4.1.1 in the reply filed on 05/25/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

However, the election has been rendered moot by Applicant's subsequent amendment, filed 07/27/2005.

2. Applicant's amendment/remarks, filed 07/27/2005, are acknowledged.

Claims 1 – 104 have been cancelled.

Claims 105 – 366 have been added.

Claims 105 – 366 are pending.

3. Sequence compliance: Applicant's amendment to the specification, adding the Sequence Listing and sequence identification numbers, filed 07/09/2004, is acknowledged. However, this amendment is insufficient to place the instant application in compliance with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth herein.

Upon review of the instant application, it is noted that the sequences disclosed at least on pages 61, 66, and 67 *are not accompanied by SEQ ID Numbers*. Applicant is reminded of the sequence rules which require a submission for all sequences of more

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than 9 nucleotides or 3 amino acids (see 37 CFR 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules. Applicant is reminded to amend the specification and the claims accordingly.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) in response to this Office Action.

4. Applicant's provision of written assurance that an acceptable deposit of hybridoma 4.1.1, which is referenced in the claims and identified in the present application will be made before payment of any issue fee and under conditions that satisfy the USPTO and the patent laws, filed 07/27/2005 (page 46 of Applicants remarks), is acknowledged.

5. Applicant's claim for domestic priority under 35 U.S.C. 119(e) and 120 is acknowledged. The provisional application USSN 60/113,647 upon which priority is claimed appears to provide adequate support under 35 U.S.C. 112 for subject matter claimed in the instant application.

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.

7. Applicant's IDS, filed 07/27/2005, is acknowledged, and has been considered.

It is noted that where only a part of the reference has been provided, only the pages indicated in the IDS have been considered (e.g. Dayhoff, 1976).

8. The use of trademarks has been noted in this application (e.g. LipofectinTM on page 47). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

9. The disclosure is objected to because of the following informalities: the specification includes apparent spelling errors.

A. The specification discloses cell lines designated "NSO0" (page 49 line 19) and "NSO" (page 68 line 5). Appropriate correction or clarification whether the cell lines are distinct is required.

B. The specification contains other apparent spelling errors, such as, for example, in the word "sythetase" on page 49, line 31. Appropriate correction is required.

Applicant is requested to proofread the specification and correct any other possible errors.

10. Claims 114, 123, 141, 149, 204, 247, 249, 251, 253, and 255, are objected to because of the following informalities: period at the end of the sentence is lacking; claim status identifier is absent, and/or other typographical or spelling errors. Appropriate correction is required.

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Applicant is requested to proofread the claims and correct any other possible errors.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 179 – 256 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 179 – 256 are indefinite in the recitation of “A method comprising ...”, because in the absence of a clear recitation of a preamble, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed methods.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

13. The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 105 – 366 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over pending claims 116 – 124, 126 – 135, 137, 148 – 169, 171 – 190, 193 – 206, 209 – 222, and 225 – 235 of copending Application USSN 10/612,497. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims 179 – 256 and claims 116 – 124, 126 – 135, 137, 148 – 169, 171 – 190, 193 – 206, 209 – 222, and 225 – 235 of copending Application USSN 10/612,497 are directed to the same or nearly the same methods of producing human monoclonal CTLA4-specific antibodies, while the instant claims 105 – 178 and 257 – 366 are directed to host cells which anticipate, and are anticipated by, the method claims of copending Application USSN 10/612,497.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Conclusion: no claim is allowed.

The claims appear to be free of prior art.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI

Patent Examiner

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September 27, 2005

PHILLIP GAMBEL
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER

TECH CENTER 1600

9/27/2005